DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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May 16, 2007

Peter J. Davies, M.D., Ph.D.
Executive Vice President for Research
University of Texas Health Science Center at Houston
7000 Fannin, UCT 1008
Houston, TX 77030

RE: Human Research Subject Protections Under Federalwide Assurance FWA- 0667

Research Project: Genetic Studies in Rheumatic and Autoimmune Diseases/An Immunogenetic Database and Storage Bank for Rheumatic and Autoimmune Diseases
Principal Investigator: Frank C. Arnett, M.D.
Project Number: HSC-MS-02-046

Research Project: The MHC and Disease Associations
Principal Investigator: Frank C. Arnett, M.D.
Project Number: IRB05-00349

Dear Dr. Davies:

The Office for Human Research Protections (OHRP) has reviewed your October 4, 2006 response to OHRP's August 28, 2006 letter outlining allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research.

The allegations involved the following:

(1) Failure to ensure that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled, as required by HHS regulations at 45 CFR 46.116(a)(8). In specific, it was alleged that the complainant was approached by her physician to enroll in the above referenced trial, she refused, and has since had problems with obtaining medical care from her UTHSCH affiliated physician. In addition, a biopsy sample taken from the complainant for a confirmatory diagnosis of autoimmune illness was lost, and it was alleged that the biopsy sample was being used for the above-referenced research without her consent.

(2) Failure to ensure that the procedures for enrolling subjects failed to minimize the possibility of coercion or undue influence as required by HHS regulations at 45 CFR 46.116. It was alleged that the complainant faced coercion or undue influence when approached about enrollment in the above-referenced studies.

Findings: OHRP's review could not substantiate either of these allegations. OHRP notes the University of Texas Health Science Center (UTHSCH) investigation of the matter found that (a) the protocol in question would have required a blood sample; (b) the clinical sample that was lost was a tissue biopsy; and (c) there was no evidence that the complainant was enrolled in the research study. OHRP also notes that the informed consent document approved by the UTHSCH institutional review board (IRB) clearly stated that involvement in the research is voluntary, that subjects may refuse to take part or stop taking part at any time and such decisions in no way effect the service that they receive at UTHSCH.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Paul J Andreason, M.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Dr Richard L. Kirkeeide, Chair, IRB#1, UTHSCH
Dr. John C. Ribble, Chair, IRB#2, UTHSCH
Dr. John W. Sparks, Chair, IRB#3, UTHSCH
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